

FOLATEN- multivitamin tablet
Oncora Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Folaten

DESCRIPTION

Folaten is a prescription multivitamin/multimineral dietary supplement.

SUPPLEMENT FACTS		
<i>Serving size</i>		<i>1 tablet</i>
<i>Amount per serving:</i>		<i>% Daily Value</i>
Vitamin A (as Beta-Carotene)	300 mcg RAE	33%
Vitamin C (as Ascorbic Acid)	60mg	67%
Vitamin D (as Cholecalciferol)	10mcg	50%
Vitamin E (as di-Alpha Tocopherol Acetate)	4.5 mg (10 IU)	33%
Vitamin B6 (as Pyridoxine HCl)	26mg	1529%
Biotin	0.280mg	933%
Folate	1.67 mg □FE	418%
(from Folic Acid)	0.67 mg □FE	
(from 5 Methyl Tetrahydrofolate Calcium Salt)	1 mg DFE	
Vitamin B12 (as Cyanocobalamin)	0.013 mg	542%
Calcium (as Calcium Carbonate)	80 mg	6%
Magnesium (as Magnesium Oxide)	25mg	6%
Ferrochel™	20mg	111mg
Iodine (as Potassium Iodide)	0.150mg	100%
Other Ingredients: Microcrystalline Cellulose, Maltodextrin, Croscarmellose Sodium, Silicon Dioxide, Stearic Acid, Magnesium Stearate, Film Coating (Hydroxypropyl Methylcellulose, Polyethylene Glycol, Titanium Dioxide, FD&C Blue# 1		

INDICATIONS AND USAGE

Folaten is a prescription multivitamin/multi-mineral dietary supplement formulated for the clinical dietary management of a suboptimal nutritional status in patients where advanced folate, vitamin B supplementation, and maintenance of good health is needed.

CONTRAINDICATIONS

Folaten is contraindicated in patients with a known hypersensitivity to any of the ingredients.

PRECAUTIONS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B 12 deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNINGS

WARNING Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.** In the case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events. To reports adverse side effects or to obtain product information, contact Oncora Pharma at 888-321-2821.

DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

HOW SUPPLIED

Bottles of 30 Tablets (85477-901-30). Tablet is tan, oblong.

STORAGE

STORAGE: Store at 20- 25 degree C (68-77 F) excursions permitted to 15-30 degree C (59-86 F) {See USP controlled Room Temperature} Avoid excessive heat, light and moisture.

TAMPER EVIDENT: Do not use if seal is broken or missing.

MADE IN USA

Distributed by:

888-321-2821

Oncora Pharma

Dallas, TX 75161

PRINCIPAL DISPLAY PANEL

85477-901-30

FolatenTM**DIETARY SUPPLEMENT****30 TABLETS**

Dispensed by Prescription

DOSAGE AND ADMINISTRATION:

Usual adult dosage is 1 tablet taken orally once daily or as prescribed by a licensed medical practitioner.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.** In case of accidental overdose, call a doctor or poison control center immediately.



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FOLATEN

multivitamin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85477-901
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	300 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	4.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.28 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.67 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.013 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.15 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	brown (tan)	Score	no score
Shape	OVAL (Oblong)	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-901-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2026	

Labeler - Oncora Pharma, LLC (119482542)